Notice of Allowability	Application No.	Applicant(s)	
	09/715,763	SHASHOUA, VICTOR E.	
	Examiner	Art Unit	
	Anand U Desai, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *August 2, 2004*.

2. ☒ The allowed claim(s) is/are *88,92,93,95-99,104-109 and 118-131*.

3. ☒ The drawings filed on *17 November 2000* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 20040802
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *20040818* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

8/18/04

Jon P. Weber, Ph.D.
Primary Examiner

DETAILED ACTION

1. This Office Action is in response to amendment filed on August 2, 2004. Claims 88, 92, 93, 95-99, and 104-109 are currently pending and are under examination.

Priority

2. Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(e). The priority date is November 18, 1999.

Oath/Declaration

3. The declaration under 37 CFR 1.132 filed August 2, 2004 is sufficient to overcome the rejection of claims 88, 92, 93, 95-99, 104-106, 108, and 109 based upon a specific reference applied under 35 U.S.C. 103. The declaration attributes U.S. Patent 6,627,601 to Dr. Victor E. Shashoua (Applicant), and therefore U.S. Patent 6,627,601 is not considered prior art. U.S. patent 6,627,601 is not one year prior to the date of the current application for patent in the United States, and thus does not qualify under §102(b). The declaration is not to be listed on the PTO-1449 form, but has been considered.

EXAMINER'S AMENDMENT

4. An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Min Ding on August 17, 2004.

Examiner's Amendment to the Claims:

Claims 1-87 (Canceled).

Claim 88. (Currently amended) A method of preparing a dietary supplement useful for reducing or preventing reactive oxygen species in a mammal, comprising mixing a chemical composition consisting essentially of one or more peptide compound capable of upregulating at one gene of the group consisting of the genes encoding superoxide dismutase (SOD) and catalase (CAT), with a suitable vehicle, wherein said peptide compound having more than one amino acid and having 7 or fewer than 7 amino acids.

Claims 89-91 (Canceled).

Claim 92. (Previously presented) The method according to Claim 88, wherein said peptide compound comprising the formula:

R_1 Xaa_1 Gly Xaa_2 Xaa_3 Xaa_4 Xaa_5 Xaa_6 R_2 (SEQ ID NO:3),

wherein R_1 is absent or is an amino terminal capping group of the peptide compound; Xaa_1 and Xaa_2 are, independently, aspartic acid or asparagine; Xaa_3 is absent or Gly; Xaa_4 is absent, Asp or Phe; Xaa_5 is absent, Ala, or Phe; Xaa_6 is absent or Ala; R_2 is absent or is a carboxy terminal capping group of the peptide compound.

Claim 93. (Previously presented) The method according to Claim 88, wherein said peptide compound comprising the formula:

R_1 Xaa_1 Xaa_2 Xaa_3 R_2,

wherein Xaa_1 is Asp, Asn, Glu, Gln, Thr, or Tyr; Xaa_2 is absent or any amino acid; Xaa_3 is Asp, Asn, Glu, Thr, Ser, Gly, or Leu; R_1 is absent or is an amino terminal capping group; R_2 is absent or is a carboxy terminal capping group; and wherein the peptide compound upregulates expression of a gene encoding an antioxidative enzyme.

Claim 94 (canceled).

Claim 95 (Previously presented) The method according to Claim 88, wherein the peptide compound further comprises an amino terminal capping group and/or a carboxy terminal capping group.

Claim 96 (Currently amended) The method according to Claim 95, wherein the amino terminal capping group is selected from the group consisting of:

1 to 6 lysine residues, 1 to 6 arginine residues, a glucose-3-O-glycolic acid group, an acyl group containing a hydrocarbon chain from 1 to 25 carbon atoms in length, an acetyl group, a palmitoyl group, a lipoic group, a docosahexaenoic acid group, and combinations thereof.

Claim 97 (Previously presented) The method according to Claim 95, wherein said carboxy terminal capping group is an amino group linked to the carboxy terminal carbonyl in an amide linkage.

Claim 98 (Previously presented) The method according to Claim 97, wherein said amino group is a primary or secondary amine.

Claim 99 (Currently amended) The method according to Claim 88, wherein said gene is selected from the group consisting of a gene encoding superoxide dismutase, and a gene encoding catalase.

Claims 100-103 (Canceled).

Claim 104 (Currently amended) The method as described in Claim 88, wherein said peptide compound comprising fewer than 6 amino acids.

Claim 105 (Currently amended) The method as described in Claim 88, wherein said peptide compound comprising fewer than 5 amino acids.

Claim 106 (Currently amended) The method as described in Claim 88, wherein the suitable vehicle is selected from the group consisting of a pharmaceutically acceptable excipient, salt, adjuvant along with a carrier, and a composition purified from a natural source.

Claim 107 (Previously presented) The method as described in Claim 106, wherein said natural source is selected from a group consisting of green velvet antler, deer, and elk.

Claim 108 (Previously presented) The method as described in Claim 106, wherein said natural source is selected from the group consisting of plants and microorganisms.

Claim 109 (Currently amended) The method as described in Claim 88, wherein said peptide compound is capable of upregulating the genes encoding superoxide dismutase (SOD) and catalase (CAT).

Claims 110-117 (Canceled).

Claim 118. (New) A method of preparing a pharmaceutical composition useful for reducing or preventing reactive oxygen species in a mammal, comprising mixing a chemical composition consisting essentially of one or more peptide compound capable of upregulating at one gene of the group consisting of the genes encoding superoxide dismutase (SOD) and catalase (CAT), with a suitable vehicle, wherein said peptide compound having more than one amino acid and having 7 or fewer than 7 amino acids.

Claim 119. (New) The method according to Claim 118, wherein said peptide compound comprising the formula:

R_1 Xaa_1 Gly Xaa_2 Xaa_3 Xaa_4 Xaa_5 Xaa_6 R_2 (SEQ ID NO:3),

wherein R_1 is absent or is an amino terminal capping group of the peptide compound; Xaa_1 and Xaa_2 are, independently, aspartic acid or asparagine; Xaa_3 is absent or Gly; Xaa_4 is absent, Asp or Phe; Xaa_5 is absent, Ala, or Phe; Xaa_6 is absent or Ala; R_2 is absent or is a carboxy terminal capping group of the peptide compound.

Claim 120. (New) The method according to Claim 118, wherein said peptide compound comprising the formula:

R_1 Xaa_1 Xaa_2 Xaa_3 R_2,

wherein Xaa_1 is Asp, Asn, Glu, Gln, Thr, or Tyr; Xaa_2 is absent or any amino acid; Xaa_3 is Asp, Asn, Glu, Thr, Ser, Gly, or Leu; R_1 is absent or is an amino terminal capping group; R_2 is absent or is a carboxy terminal capping group; and wherein the peptide compound upregulates expression of a gene encoding an antioxidative enzyme.

Claim 121 (New) The method according to Claim 118, wherein the peptide compound further comprises an amino terminal capping group and/or a carboxy terminal capping group.

Claim 122 (New) The method according to Claim 121, wherein the amino terminal capping group is selected from the group consisting of:

1 to 6 lysine residues, 1 to 6 arginine residues, a glucose-3-O-glycolic acid group, an acyl group containing a hydrocarbon chain from 1 to 25 carbon atoms in length, an acetyl group, a palmitoyl group, a lipoic group, a docosahexaenoic acid group, and combinations thereof.

Claim 123 (New) The method according to Claim 121, wherein said carboxy terminal capping group is an amino group linked to the carboxy terminal carbonyl in an amide linkage.

Claim 124 (New) The method according to Claim 123, wherein said amino group is a primary or secondary amine.

Claim 125 (New) The method according to Claim 118, wherein said gene is selected from the group consisting of a gene encoding superoxide dismutase, and a gene encoding catalase.

Claim 126 (New) The method as described in Claim 118, wherein said peptide compound comprising fewer than 6 amino acids.

Claim 127 (New) The method as described in Claim 118, wherein said peptide compound comprising fewer than 5 amino acids.

Claim 128 (New) The method as described in Claim 118, wherein the suitable vehicle is selected from the group consisting of a pharmaceutically acceptable excipient, salt, adjuvant along with a carrier, and a composition purified from a natural source.

Claim 129 (New) The method as described in Claim 128, wherein said natural source is selected from a group consisting of green velvet antler, deer, and elk.

Claim 130 (New) The method as described in Claim 128, wherein said natural source is selected from the group consisting of plants and microorganisms.

Claim 131 (New) The method as described in Claim 118, wherein said peptide compound is capable of upregulating the genes encoding superoxide dismutase (SOD) and catalase (CAT).

Claim Objections

5. Upon review of Applicant's amendment the objection to claims 88, and 109 are withdrawn.

Claim Rejections - 35 USC § 103

6. Upon review of Applicant's amendment to remove the limitation of glutathione peroxidase there is no outstanding 35 USC § 103 rejection.

Allowable Subject Matter

7. Claims 88, 92, 93, 95-99, 104-109, and 118-131 are allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statements of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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August 19, 2004